

**R E M A R K S**

Claims 1-30 are pending in the present application. The following rejections are at issue and are set forth by number in the order in which they are addressed:

1. Claims 1-30 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of U.S. Patent No. 6,015,833 in view of Cook et al. U.S. Patent No. 5,760,082; and
2. Claims 1-30 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594);

Applicants believe that the amendments and remarks present herein traverse all of the Examiner's remaining rejections.

**1. The Double Patenting Rejection Is Improper**

Applicants contend that the double patenting rejection is not proper for the reasons stated in the prior Response and Amendment. Nevertheless, Applicants herein offer to submit a Terminal Disclaimer over the U.S. 6,015,833 upon the Examiner's indication of patentable subject matter in the instant application.

**2. The Examiner Has Failed to Establish a *Prima Facie* Case of Obviousness**

Claims 1-30 are rejected under 35 U.S.C. §103(a) as allegedly being obvious under Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594).<sup>1</sup> Applicants must respectfully disagree.

A *prima facie* case of obviousness requires the Examiner to cite a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in

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<sup>1</sup> Applicants respectfully note that the Examiner has withdrawn the Lievense (U.S. 6,159,525) reference from the pending obviousness rejection.

issue.<sup>2</sup> In addressing this rejection, Applicants focus on the independent claims since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent therefrom.<sup>3</sup>

#### A. No Motivation To Combine The References

When applying 35 U.S.C. §103, the references must be considered as whole and must suggest the desirability and thus the obviousness of making the combination.<sup>4</sup> Applicants further submit that references cannot be considered collectively until the Examiner points to some motivation to combine those references. The purpose behind this requirement is to prevent the Examiner from using the invention itself and hindsight reconstruction to defeat the patentability of the invention. The Federal Circuit, in a recent decision, articulates this position:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.<sup>5</sup>

The references do not suggest the desirability of making the combination. The Examiner states that:

Cain et al. teaches that it is well known in the art that antioxidants, such as vitamin E or BHT, is known to be useful in food products containing conjugated lineolic acid compounds . . . . Baltes teaches that isomerization of lineolic acid compounds to conjugated lineolic acid compounds by alcoholate catalysts. . . . Therefore, it would have been prima facie obvious to a person of ordinary skill in the art . . . to incorporate conjugated linoleic acid derivatives, including esters, as well as antioxidant in food product [sic].<sup>6</sup>

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<sup>2</sup> See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

<sup>3</sup> §MPEP 2143.03.

<sup>4</sup> *Hodash v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143, n. 5, 229 USPQ 182, 187, n.5 (Fed. Cir. 1986).

<sup>5</sup> See, *In re Rouffet et al.*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998).

<sup>6</sup> Office Action, p. 4.

Applicants respectfully submit that by making these statements, the Examiner has not shown reasons why a skilled artisan would make the combination; he has only stated what he believes each reference teaches in isolation from the other reference and then stated that it would be obvious to combine the elements. In order to support the combination, the Examiner has merely relied on the level of skill in the art. This is not permissible. Such unsupported statements are exactly what the *Rouffet* court sought to prevent. The Federal Circuit stated:

The Board did not . . . explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technological advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.<sup>7</sup>

The Examiner has not "shown reasons" why there is a motivation to combine. By simply reciting a list of elements and citing Baltes et al., the Examiner is apparently relying on the high level of skill in the art to guide the modification. Applicants can find no other reasoning supporting a motivation to combine. The Examiner's apparent reliance on the high level of skill in the art is expressly forbidden by the Federal Circuit.

Cook et al. describe production of conjugated linoleic acids by using KOH or NaOH and ethylene glycol (see e.g., *col. 2, ll. 20-27* and *col. 5, ll. 38-46*). There is NO suggestion in any of the references, nor anywhere else outside of the Applicants' specification, of a **method** for producing a food product containing conjugated linoleic acid products comprising providing conjugated linoleic acid products which are obtained from or derived from conjugated linoleic acid esters produced by treating linoleic acid esters with an alcoholate catalyst, as is claimed in the present invention.

Furthermore, when one examines the Baltes et al. reference, it is clear that there could be no motivation to combine the reference to produce the presently claimed invention. In particular, Baltes et al. describes a method of alcoholate catalysis for producing conjugated

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<sup>7</sup> *Rouffet*, 47 USPQ2d at 1458.

linoleic acids; the products are described as "valuable industrial products" for use in formation of "light colored polymers," for use as "ingredients of lacquers or coating compositions" or as "ingredients of plasticizers" and as "reaction components in the preparation of resins" (Baltes et al., *col. 9, ll. 47-60*). Nothing in the Baltes et al. reference teaches or suggest the desirability of employing its methods for producing sort of food products.

The Baltes reference is directed to the production of substitutes for tung oil, which is not suitable for oral consumption. These substitutes for tung oil are intended for industrial uses such as for drying oils, varnishes, and lacquers. Thus, the Baltes reference actually **teaches away** from the use of CLA as for oral consumption--let alone food products made by the claimed methods--even when viewed together with the other cited references.<sup>8</sup> "A reference may be said to teach away when a person of ordinary skill, upon [examining] the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant."<sup>9</sup>

Accordingly, it is not proper to combine Baltes et al. with the other references. This argument is supported by the previously submitted Declaration of Dr. Asgeir Sæbo. As detailed in the Declaration, none of the references teach or suggest using CLA isomerized with alcoholate catalysts in a food product. As explained by Dr. Sæbo, the Baltes patent discloses the use of oils with high levels of triunsaturated fatty acids. These oils are not generally suitable for the production CLA for oral consumption.

The majority of the claims pending in this application are method claims, not composition claims. Applicants note that the Examiner has apparently failed to take into

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<sup>8</sup> Baltes et al. *col. 9, ll. 46-61* teach that:

The compounds of the conjugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in many ways. For instance their polymerisation by heating takes place at a very fast rate and therefore, the products can be converted into light colored polymer compounds by moderate heating, e.g., 260-280°C. The polymers thus formed can be used as ingredients of lacquers or coating compositions in conventional manner. Furthermore the conjugated fatty acids coumpounds of this invention can be used as ingredients of plasticizers for organic plastic materials, and as reaction components in the preparation of resins, such as alkyd resins or maleinate resins, in conventional manner.

<sup>9</sup> *In re Para-Ordnance Manufacturing v. SGS Importers International*, 37 USPQ2d 1237, 1241 (Fed. Cir. 1995) (quoting *In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

consideration the fact the conjugated linoleic acid produced by the methods of the present invention differ in composition from other conjugated linoleic acid products. These differences are claimed, for example, in Claims 25-30 and described in the Specification at pages 18 and 19.

For the reasons stated above, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and therefore respectfully request that this rejection be withdrawn.

**B. References Do Not Teach All Of The Elements Of The Claims**

In their previous Amendment and Response, Applicants made extensive arguments regarding the failure of the references to provide all of the elements of the Claims. The Examiner has failed to address Applicants arguments regarding alcohols. In particular, the Applicants argued that:

Moreover, none of the references teach or even suggest a food product comprising a conjugated linoleic acid moiety and an **alcohol**, as does the claimed invention, nor does the Examiner assert that they do. The Examiner simply concludes that the "employment of alcohol herein is seen to employment of a known food ingredient to a food product and therefore is obvious" (Office Action page 4). Thus, the references even in combination do not teach all of the elements of Claim 25, and thus do not teach all of the elements in its dependent Claims 26-30. Therefore, these claims are not obvious over the cited references as well.

The Examiner has responded to the Applicant's arguments by conclusively arguing that alcohol in foods is well known. The Examiner has again failed to make the required showing that the cited references teach every element of the present claims.

Applicants further note that the Examiner's failure to adequately respond to their argument is problematic and dilatory to their business interest and the prosecution of the present claims. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**C. The Cited References Do Not Provide Reasonable Expectation Of Success**

The cited references do not provide a reasonable expectation of success for obtaining the claimed methods. The Federal Circuit has held that "obvious to experiment" is not the

standard for obviousness.<sup>10</sup> The Court in *In re Dow Chemical* made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art."<sup>11</sup>

Applicants submit that one skilled in the art would not believe that a reasonable expectation of success existed for arriving at the claimed invention. As described above, each of the claims contains the element of utilizing an alcoholate catalyst to produce conjugated linoleic acid. The conjugated linoleic acid is then used to produce a product for oral consumption such as a food product. As described in the Declaration of Dr. Asgeir Sæbo, one of skill in the art, upon reading the three cited references, could not conclude that CLA produced by the alcoholate catalysis method would be suitable for use in products meant for oral consumption. Cook makes absolutely no reference to this method, and Baltes is solely directed to the production of conjugated fatty acids for industrial uses such as in varnishes and lacquers. Given this completely different use, a person skilled in the art could not conclude from the three cited references that the alcoholate catalysis method would be suitable for use in the production of CLA meant for biological uses. Therefore, the Examiner's use of Baltes to show the level of skill in the art is inappropriate. Baltes may show the level of skill in the art of the production of drying oils for use in varnishes and lacquers, but it is not useful for showing the level of skill in the art of nutrition. The other cited references do not cure this deficiency. Accordingly, the references do not establish a reasonable expectation of success. Therefore, a *prima facie* case of obviousness has not been established and the claims should be passed to allowance.

### **3. The Declaration Of Dr. Asgeir Sæbo**

The Examiner states that the Declaration of Dr. Sæbo has been considered but found unpersuasive.<sup>12</sup> In particular, the Examiner argues that "applicant appears to argue the employment of the reaction mixture to foodstuff, what is actually in the claims are the

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<sup>10</sup> *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988).

<sup>11</sup> *Id.* at 1531; emphasis added.

<sup>12</sup> Office Action, p. 5.

compounds, i.e., conjugated linoleic esters. [sic.] ('to provide conjugated lineolic acid esters', see the claims in the instant application)."<sup>13</sup> Applicants respectfully disagree with the Examiner's conclusion. The present claims do in fact recite foodstuffs.

The Examiner's **conclusory** statement indicates a failure to respond to Applicants' traversals and to accord due weight to Dr. Sæbo's Declaration. Moreover, the Examiner's failure to accept Dr. Sæbo's Declaration--without providing substantial contrary evidence--is not looked upon with favor by the Federal Circuit and does not conform with proper patent practice according the Manual of Patent Examining Procedure. The MPEP requires that:

**Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . In re Beattie**, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

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A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. See, e.g., *Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. See, e.g., *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.<sup>14</sup>

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over . . . . An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.<sup>15</sup>

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<sup>13</sup> Office Action, p. 5.

<sup>14</sup> MPEP §§2144.08; emphasis added).


<sup>15</sup> *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

Accordingly, the Examiner should reconsider the fact based Declaration of Dr.Sæbo, and absent substantial evidence contrary to the Declaration, withdraw this rejection and pass the pending Claims to allowance.

**C O N C L U S I O N**

All grounds of rejection and objection of the Office Action of December 28, 2001, having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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**APPENDIX I**

**Clean Version Of The Entire Set Of Pending Claims As  
Amended In This Communication**

1. (Amended once) A method for producing a food product containing conjugated linoleic acid esters comprising:
  - a) providing:
    - i) linoleic acid esters,
    - ii) an alcoholate catalyst,
    - iii) a foodstuff;
  - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters; and
  - c) combining said foodstuff with said conjugated linoleic acid esters to produce a food product.
2. The method of Claim 1, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.
3. (Amended once) The method of Claim 1, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.
4. (Amended Once) The method of Claim 1, further comprising providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (b) to produce said food product.
5. (Amended Once) The method of Claim 4, wherein said antioxidant is selected from the group consisting of  $\alpha$ -tocopherol,  $\beta$ -tocopherol, lecithin, ascorbylpalmitate, and BHT.
6. (Amended Twice) The food product produced according to the method of Claim 1, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

7. (Amended Twice) A method for producing a food product containing conjugated linoleic acid comprising:

- a) providing:
  - i) linoleic acid esters,
  - ii) an alcoholate catalyst,
  - iii) a foodstuff;
- b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
- c) treating said conjugated linoleic acid esters to provide conjugated linoleic acid; and
- d) combining said foodstuff with said conjugated linoleic acid to produce a food product.

8. The method of Claim 7, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

9. (Amended once) The method of Claim 7, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate

10. (Amended Once) The method of Claim 7, further comprising providing an antioxidant and combining said antioxidant with said conjugated linoleic acid and said foodstuff in step (b) to produce said food product.

11. (Amended Once) The method of Claim 10, wherein said antioxidant is selected from the group consisting of  $\alpha$ -tocopherol,  $\beta$ -tocopherol, lecithin, ascorbylpalmitate, and BHT.

12. (Amended Twice) The food product produced according to the method of Claim 7, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

13. (Amended Once) A method for producing a food product containing conjugated linoleic acid triglycerides comprising:

- a) providing:
  - i) linoleic acid esters,
  - ii) an alcoholate catalyst, and
  - iii) a foodstuff; and
- b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
- c) incorporating said linoleic acid esters into triglycerides to provide triglycerides containing conjugated linoleic acid moieties; and
- d) combining said foodstuff with said triglycerides containing conjugated linoleic acid moieties to produce a food product.

14. The method of Claim 13, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

15. (Amended once) The method of Claim 13, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

16. (Amended Once) The method of Claim 13, further comprising providing an antioxidant and combining said antioxidant with said triglycerides and said foodstuff in step (b) to produce said food product.

17. (Amended Once) The method of Claim 16, wherein said antioxidant is selected from the group consisting of  $\alpha$ -tocopherol,  $\beta$ -tocopherol, lecithin, ascorbylpalmitate, and BHT.

18. (Amended Twice) The food product produced according to the method of Claim 13, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

19. (Amended Once) A method for producing a food product comprising:
- a) providing:
    - i) linoleic acid esters;
    - ii) an alcoholate catalyst; and
    - iii) a foodstuff;
  - b) producing a conjugated linoleic acid esters by treating said linoleic acid esters with said alcoholate catalyst; and
  - c) combining said conjugated linoleic acid esters with said foodstuff to produce a food product.
20. The method of Claim 19, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.
21. (Amended once) The method of Claim 19, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.
22. The method of Claim 19, further comprising providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (c) to produce said food product.
23. (Amended Once) The method of Claim 22, wherein said antioxidant is selected from the group consisting of  $\alpha$ -tocopherol,  $\beta$ -tocopherol, lecithin, ascorbylpalmitate, and BHT.
24. (Amended Twice) The food product produced according to the method of Claim 19, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.
25. A food product comprising a conjugated linoleic acid moiety and an alcohol.
26. The food product of Claim 25, wherein said alcohol is ethyl alcohol.

27. The food product of Claim 25, wherein said alcohol is present in a concentration of about less than 10 ppm.

28. The food product of Claim 25, wherein said conjugated linoleic acid moiety is an ester of conjugated linoleic acid.

29. The food product of Claim 25, wherein said conjugated linoleic acid moiety is a free fatty acid.

30. The food product of Claim 25, wherein said conjugated linoleic acid moiety is a triglyceride.